

K061860

SEP 18 2006

**Quality Assurance Department**

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Date: June 28, 2006

**510(k) Summary**

**3-1. 510(k) owner (submitter)**

- |                           |   |
|---------------------------|---|
| 1) Name                   | KURARAY MEDICAL INC.  |
| 2) Address                | 1621 Sakazu, Kurashiki, Okayama 710-0801, Japan   |
| 3) Contact person         | Michio Takigawa<br>Quality Assurance Department   |
| 4) Contact person in U.S. | Koji Nishida<br>KURARAY AMERICA INC.<br>101 East 52nd Street, 26th Floor<br>New York, NY 10022<br>Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676<br>Fax: (212)-867-3543 |

**3-2. Name of Device**

- |                             |  |
|-----------------------------|--|
| 1) Trade / Proprietary name | CLEARFIL MAJESTY Esthetic  |
| 2) Classification name      | Tooth shade resin material<br>(21 CFR section 872.3690. Product code: EBF) |
| 3) Common name              | Restorative composite resin  |

**3-3. Predicate device**

- |                    |   |
|--------------------|---|
| 1) CLEARFIL AP-X   | 510(k) Number: K012740<br>Product Code: EBF<br>21 CFR Section: 872.3690<br>Applicant: KURARAY MEDICAL INC.  |
| 2) EPRICORD        | 510(k) Number: K033267<br>Product Code: EBF<br>21 CFR Section: 872.3690<br>Applicant: KURARAY MEDICAL INC.  |
| 3) GRADIA DIRECT   | 510(k) Number: K023814<br>Product Code: EBF<br>21 CFR Section: 872.3690<br>Applicant: GC AMERICA, INC.      |
| 4) TETRIC EVOCERAM | 510(k) Number: K042819<br>Product Code: EBF<br>21 CFR Section: 872.3690<br>Applicant: IVOCAR VIVADENT, INC. |

### 3-4. Description of device

CLEARFIL MAJESTY Esthetic is a light-cure, radiopaque restorative composite resin which provides accurate color matching, high polish ability and excellent physical properties, making it ideal for both anterior and posterior restorations. It is formulated with optimal viscosity assuring easy handling and placement.

It is classified into tooth shade resin material (21 CFR section 872.3690, Product code: EBF ) according to 21 CFR § 872 since it is composed of materials such as 2,2'-Bis-[p-( $\gamma$ -methacryloxy- $\beta$ -hydroxypropoxy) phenyl] propane (Bis-GMA).

According to the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry - Polymer-based filling, restorative and luting materials", this device is classified into the following:

- Type 1: polymer-based filling and restorative materials;
- Class 2: materials whose setting is effected by light;
- Group 1: materials whose use requires the energy to be applied intra-orally.

### 3-5. Intended uses

It is intended to be used for the indications listed in the left hand column of the below table that are equivalent to the predicate devices.

Table 3: Indications for Use and predicate devices

Indications for Use	Predicate devices
1) Direct restorations for anterior and posterior teeth (Class I – V cavities)	CLEARFIL AP-X, TETRIC EVOCERAM, GRADIA DIRECT
2) Direct veneers	TETRIC EVOCERAM, GRADIA DIRECT
3) Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)	GRADIA DIRECT
4) Intraoral repairs of fractured crowns/bridges	TETRIC EVOCERAM

### 3-6. Technological characteristics of device

#### 1) Effectiveness / Performance

CLEARFIL MAJESTY Esthetic, the applicant device, is verified to comply with the requirements of the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry - Polymer-based filling, restorative and luting materials". As to compare with the predicate devices according to ISO 4049: 2000, the applicant and the predicate devices comply with ISO 4049: 2000 indicating that the applicant device is as effective as and performs as well as the predicate devices.

#### 2) Chemical ingredients

All the chemical ingredients of CLEARFIL MAJESTY Esthetic, the applicant device, have been used in the predicate devices indicating that the safety of the applicant device is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 18 2006

Kuraray Medical, Incorporated  
C/O Mr. Koji Nishida  
General Manager  
Kuraray America, Incorporated  
101 East 52<sup>nd</sup> Street, 26<sup>th</sup> Floor  
New York, New York 10022

Re: K061860  
Trade/Device Name: CLEARFIL MAJESTY Esthetic  
Regulation Number: 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: II  
Product Code: EBF  
Dated: June 28, 2006  
Received: July 11, 2006

Dear Mr. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish extending to the right.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K061860

Device Name: CLEARFIL MAJESTY Esthetic

Indications for Use:

- 1) Direct restorations for anterior and posterior teeth (Class I – V cavities)
- 2) Direct veneers
- 3) Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
- 4) Intraoral repairs of fractured crowns/bridges

Prescription Use X AND/OR Over-The-Counter Use N/A  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Quinlan  
(Sign-Off)  
Division of Anesthesiology, General Hospital,  
Person Control, Dental Devices  
Number: K061860